



## PRESS RELEASE

15 November 2011

# THE EUROPEAN *IN VITRO* DIAGNOSTIC (IVD) MARKET IN 2010

The European Diagnostic Manufacturers Association (EDMA) today released its estimates for the 2010 revenues generated by the IVD industry in Europe. The IVD market revenues of € 10.5 billion represent only 0.8% of the Total Healthcare Expenditure.

*Brussels, 15 November 2011* – The EDMA figures include macroeconomic and healthcare expenditure data for all EU 27 Member States, as well as for the European Free Trade Association (EFTA).

Major growth was registered in cardiology testing and diabetes. A very strong double-digit growth was observed in the segment related to the management of hospital acquired infections, whereas all other testing areas were stagnant or negative (i.e. routine clinical chemistry and haematology). This explains why revenue growth in 2010 versus 2009 equalled 2%, therefore significantly below the figure recorded in the previous year (3.0%). European average IVD sales as of Total Healthcare Expenditure (THE) remained stable at 0.8%, whereas IVD expenditure per capita reached € 20.6 (therefore slightly increasing from € 20.1).

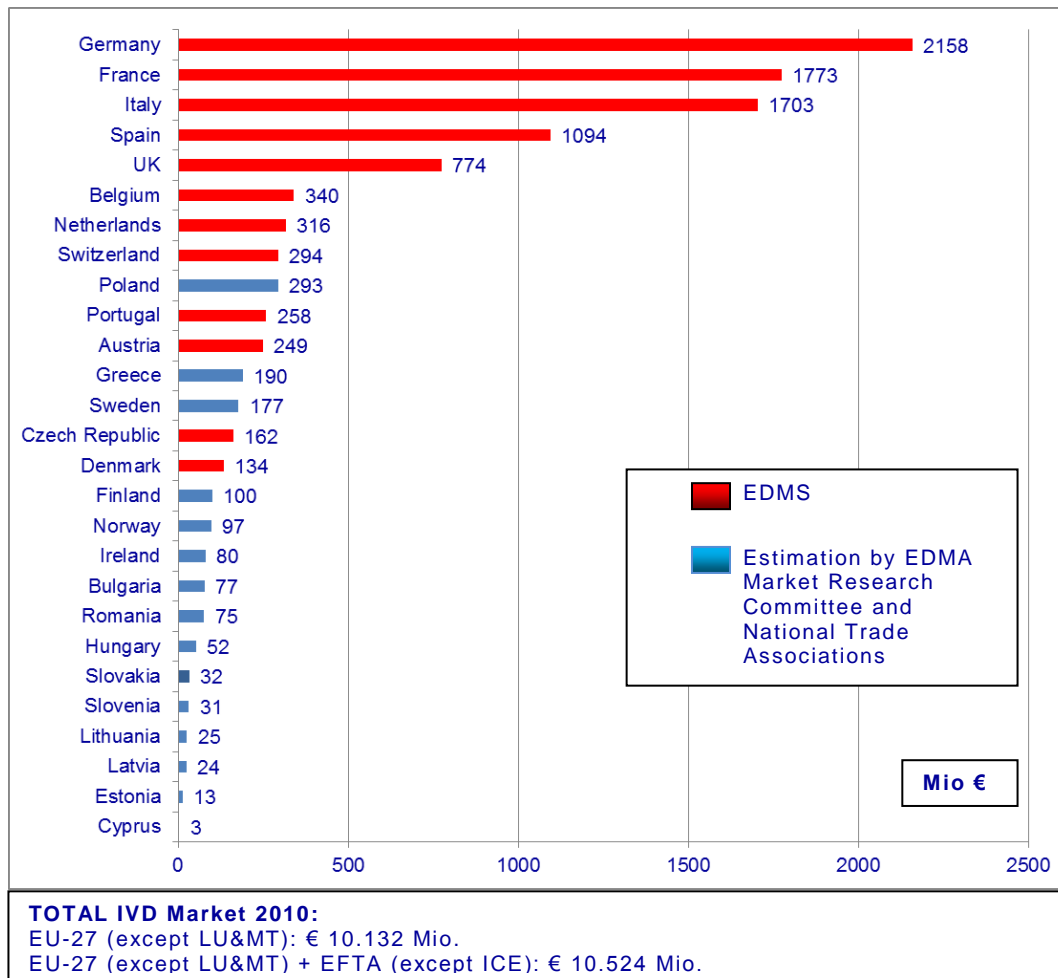
It is estimated that over 60% of the information held on the patient record comes from diagnostic tests. Despite this figure and the growing awareness that IVD testing is a cost-efficient way of providing information required for earlier diagnosis and management of many diseases, governments around Europe in 2010 have continued, in the attempt to balance budgets, to apply short-sighted limitations on testing volumes and reimbursement.

**Germany:** In 2010, Germany maintained its position as largest European IVD Market, preceding France and Italy. However, local IVD manufactures saw a slight decrease of revenues (-0.1%) compared to 2009. This was due to a negative trend in the blood tests strips segment as the Federal Joint Committee (Gemeinsamer Bundesausschuss) decided to discontinue reimbursement through the statutory health insurance<sup>1</sup> of blood sugar strips for patients suffering from diabetes mellitus 2 who are not treated with insulin.

**France:** The French government announced in January 2010 new rules regarding private laboratories (Ordonnance n° 2010-49 of 13 January 2010 related to medical biology), which allow the consolidation of private laboratories. These new rules accelerated physical consolidation of labs as well as procurement consolidation. Total market growth was mainly due to glucose self-testing (+6.40%). Despite robust volume trends, the market without glucose showed a practically flat growth and has seen massive price decreases (from 4 to 28% on 14 key parameters) and significant development on Cost Per Reportable Result (CPRR). Price decrease, development of CPRR combined with more demanding customers created unfavourable conditions for IVD suppliers.

**Italy:** Revenue growth amounted to 1.1%. Both the public hospital and the private laboratory markets faced measures to contain healthcare costs and to centralise purchasing. One of the major challenges for the IVD industry remained, however, late payment. Some regions (especially the southern ones) reached peaks of 700 days, forcing both private laboratories and IVD companies (especially SMEs) out of business.

<sup>1</sup> 90% of the German population is covered by the Statutory Health Insurance whilst the remaining 10% is covered by various private insurance schemes.



**Spain:** The market grew by only 0.5%. This relatively modest growth was due to extreme price pressure. The issue of late payment, affecting other Mediterranean countries, touched Spain too. Tender centralisation and further predicted restrictions are expected to pose several challenges to Spanish IVD manufacturers.

**UK:** The UK remains a peculiar case in the EU-27 scenario as there are currently no plans for a 'reimbursement' system for IVDs. There is, nonetheless, continuing pressure to reduce the costs of the pathology service and this is leading to consolidation of laboratories. In addition, there are targets for reducing the overall spend on goods and services for the whole of the National Health Service (NHS) alongside of the introduction of legislation, which will make very significant changes in the way the NHS operates. Traditionally, almost all laboratory-based IVD testing in the UK takes place in NHS laboratories, which are part of NHS hospitals. However, there continues to be an increasing trend towards the private sector either in joint ventures with the NHS or as private laboratory services. In addition, NHS hospitals are purchasing laboratory services from providers in the form of comprehensive Managed Service Contracts, which transfer all risk associated with service provision to a single lead supplier, and also save them VAT, as this does not apply to services.

**Switzerland:** The reimbursement rates of IVD tests performed in doctors' offices have been reduced by the Federal Government. As a consequence, for financial reasons, a number of doctors' office laboratories ceased to operate, creating a transfer of testing to larger commercial laboratories. This explains the 1.6% decline of the market.

**Portugal:** In 2010, the Portuguese IVD market decreased by 1.0%. The Stability and Growth programme contained a number of measures that impacted negatively on the IVD industry. In particular, the revision of the list of reimbursed tests, the reduction of reimbursement levels and the introduction of mandatory electronic prescriptions led to a decrease in the prescription of tests. Moreover, the concentration of the public hospitals and the arrival of international laboratory chains on the Portuguese market created new rules on the negotiations for both public tenders and the private sector. As for Italy, Spain

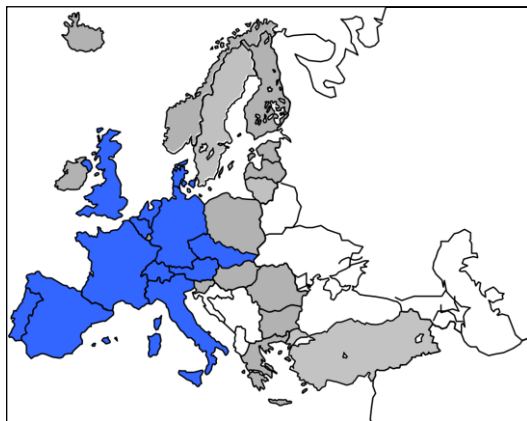
and Greece, a crucial challenge for the diagnostics industry in Portugal consisted of late payment, with the national average reaching 379 days.

**Austria:** Growth in Austria equalled 2%. The relatively moderate trend was influenced by a flat market in blood glucose monitoring, which makes up for almost 20% of the local market. No new major players entered the market and despite the fact that all companies were under heavy price pressure, the scenario did not change significantly. Some major tenders in hospitals (which usually result in lower prices and hence have an impact on market growth) were however shifted to 2011.

**Greece:** Greece has entered a period of deep recession and since April 2010 is under the strict surveillance of the EU and the IMF. Most testing takes place in public hospitals and laboratories and, in the context of the current economic crisis, a series of changes has been introduced, reducing reimbursement dramatically, both with regards to new and old tests alike, and restricting testing volumes and budgets. The chronic deficit in health funding experienced for the last 16 years has resulted in the longest payment delays across Europe (i.e. around 1400 days). The target for 2010 was to reduce the relevant expenditure by 50%, and the 2011 budgets provide for a further 50% reduction as the Public Health deficit is considered a basic constituent of the general deficit by the EU and IMF. Among the changes announced are a new public hospitals supplies' system, involving centralised supplies by a private contractor, mergers of public hospitals and the implementation of price control mechanisms by the Ministry of Health. A DRG (Diagnostic Related Groups) system will be introduced to Greek hospitals.

**Hungary:** A cap is foreseen in the budget for laboratory tests, and it was the same figure in HUF like in the previous years since 2002. The main cause of the negative revenue trend (-4.2%) is to be linked with the increased energy and labour costs. Consequently the share of reagents in the fixed budget was reduced.

The results presented below are based on individual estimates made in 27 European countries and EFTA:



- 12 countries participating in the European Diagnostic Market Statistics (EDMS) programme: *Austria, Belgium, Czech Republic, Denmark, France, Germany, Italy, Portugal, Spain, Switzerland, the Netherlands, and the UK.*
- The National Association Members of EDMA and the EDMA Market Research Committee have estimated the IVD market in 15 other countries not participating in the EDMS programme: *Bulgaria, Cyprus, Estonia, Finland, Greece, Hungary, Ireland, Latvia, Lithuania, Norway, Poland, Romania, Slovakia, Slovenia, and Sweden.*

The EDMA figures per country are compiled from the “*European Diagnostic Market Statistics*” (EDMS) programme (where companies report invoiced sales of reagents, instruments and consumables to an independent auditor, CIP, based on the EDMA Classification), in association with the EDMA Market Research Committee and the National Associations members of EDMA.

More than 85% of the market is covered by EDMS, ensuring the reliability and objectiveness of the information provided by EDMA and its members. EDMA encourages all companies and countries to participate to the EDMS programme, which is the largest *In Vitro* Diagnostic audit in Europe and the most accurate source of information to understand and predict market trends.

| Countries                     | Population 10    | GDP               | GDP / capita | THE              | THE / capita | THE as % GDP  | IVD mkt. 10      | IVD mkt. growth rate 09-10 | IVD mkt. / THE | IVD mkt. / capita |
|-------------------------------|------------------|-------------------|--------------|------------------|--------------|---------------|------------------|----------------------------|----------------|-------------------|
|                               | 000              | Mio €             | €            | Mio €            | €            | %             | Mio €            | %                          | %              | €                 |
|                               | Source OECD 2009 |                   |              |                  |              |               | Source EDMA      |                            |                |                   |
| Germany                       | 82,834           | 2,397,100         | 29,268       | 278,345          | 3,399        | 11.6%         | 2,157.91         | -0.1%                      | 0.8%           | 26.1              |
| France                        | 62,451           | 1,907,145         | 30,448       | 224,699          | 3,587        | 11.8%         | 1,773.00         | 4.2%                       | 0.8%           | 28.4              |
| UK*                           | 61,349           | 1,626,627         | 26,696       | 159,095          | 2,611        | 9.8%          | 773.85           | 6.2%                       | 0.5%           | 12.6              |
| Italy                         | 59,018           | 1,519,702         | 25,781       | 143,998          | 2,443        | 9.5%          | 1,702.50         | 1.1%                       | 1.2%           | 28.8              |
| Spain                         | 46,073           | 1,503,974         | 32,746       | 100,231          | 2,182        | 6.7%          | 1,093.70         | 0.5%                       | 1.1%           | 23.7              |
| Netherlands                   | 16,448           | 571,979           | 34,839       | 68,413           | 4,167        | 12.0%         | 315.80           | 2.2%                       | 0.5%           | 19.2              |
| Greece                        | 11,284           | 235,017           | 20,829       | 21,893           | 1,940        | 9.3%          | 190.00           | -13.6%                     | 0.9%           | 16.8              |
| Portugal                      | 10,665           | 168,610           | 15,862       | 17,287           | 1,626        | 10.3%         | 258.00           | -0.8%                      | 1.5%           | 24.2              |
| Belgium                       | 10,556           | 339,162           | 31,416       | 36,886           | 3,417        | 10.9%         | 340.00           | 1.8%                       | 0.9%           | 32.2              |
| Sweden                        | 9,385            | 320,685           | 34,479       | 32,458           | 3,490        | 10.1%         | 177.28           | 4.0%                       | 0.5%           | 18.9              |
| Austria                       | 8,388            | 274,320           | 32,802       | 30,308           | 3,624        | 11.0%         | 249.00           | 2.0%                       | 0.8%           | 29.7              |
| Denmark                       | 5,544            | 222,634           | 40,339       | 25,649           | 4,647        | 11.5%         | 134.29           | 2.6%                       | 0.5%           | 24.2              |
| Finland                       | 5,363            | 171,193           | 32,065       | 15,674           | 2,936        | 9.2%          | 99.96            | 2.0%                       | 0.6%           | 18.6              |
| Ireland                       | 4,470            | 159,645           | 35,803       | 15,222           | 3,414        | 9.5%          | 80.00            | -3.6%                      | 0.5%           | 17.9              |
| Luxembourg                    | 502              | 38,072            | 77,225       | 2,957            | 5,998        | 7.8%          |                  |                            |                |                   |
| <b>EU-15</b>                  | <b>394,330</b>   | <b>11,455,865</b> |              | <b>1,173,114</b> | <b>2,985</b> | <b>10.24%</b> | <b>9,345.29</b>  | <b>1.5%</b>                | <b>0.8%</b>    | <b>23.7</b>       |
| Poland                        | 38,187           | 338,302           | 8,867        | 24,846           | 651          | 7.3%          | 292.95           | 8.2%                       | 1.2%           | 7.7               |
| Romania                       | 21,462           | 117,071           | 5,445        | 5,364            | 249          | 4.6%          | 75.00            | 10.3%                      | 1.4%           | 3.5               |
| Czech Rep                     | 10,517           | 143,584           | 13,980       | 11,836           | 1,152        | 8.2%          | 162.36           | 4.1%                       | 1.4%           | 15.4              |
| Hungary                       | 10,000           | 94,985            | 9,465        | 7,065            | 704          | 7.4%          | 51.87            | -4.0%                      | 0.7%           | 5.2               |
| Bulgaria                      | 7,564            | 33,906            | 4,457        | 1,877            | 247          | 5.5%          | 76.80            | 3.5%                       | 4.1%           | 10.2              |
| Slovakia                      | 5,425            | 63,050            | 11,682       | 5,747            | 1,065        | 9.1%          | 31.62            | 2.0%                       | 0.6%           | 5.8               |
| Lithuania                     | 3,329            | 26,811            | 8,003        | 2,008            | 599          | 7.5%          | 25.22            | 1.0%                       | 1.3%           | 7.6               |
| Latvia                        | 2,248            | 18,767            | 8,300        | 977              | 432          | 5.2%          | 24.22            | 0.5%                       | 2.5%           | 10.8              |
| Slovenia                      | 2,025            | 35,384            | 17,517       | 3,279            | 1,623        | 9.3%          | 31.20            | 4.0%                       | 1.0%           | 15.4              |
| Estonia                       | 1,339            | 886               | 661          | 62               | 46           | 7.0%          | 13.23            | 2.0%                       | 21.3%          | 9.9               |
| Cyprus                        | 803              | 16,947            | 21,263       | 899              | 1,128        | 5.3%          | 3.06             | 2.0%                       | 0.3%           | 3.8               |
| Malta                         | 414              | 5,712             | 13,797       | 419              | 1,012        | 7.3%          |                  |                            |                |                   |
| <b>EU-27 (EU-15 + new MS)</b> | <b>497,643</b>   | <b>12,351,270</b> |              | <b>1,237,493</b> | <b>2,494</b> | <b>10.0%</b>  | <b>10,132.82</b> | <b>1.7%</b>                | <b>0.8%</b>    | <b>20.4</b>       |
| Switzerland*                  | 7,822            | 387,914           | 50,092       | 44,197           | 5,707        | 11.4%         | 294.22           | -1.6%                      | 0.7%           | 37.6              |
| Norway                        | 4,889            | 297,487           | 61,604       | 28,569           | 5,916        | 9.6%          | 97.21            | 2.5%                       | 0.3%           | 19.9              |
| Iceland                       | 318              | 9,091             | 28,500       | 878              | 2,751        | 9.7%          |                  |                            |                |                   |
| <b>TOTAL (EU-27 + EFTA)</b>   | <b>510,672</b>   | <b>13,045,762</b> |              | <b>1,311,136</b> | <b>2,576</b> | <b>10.1%</b>  | <b>10,524</b>    | <b>1.5%</b>                | <b>0.8%</b>    | <b>20.6</b>       |

## Notes:

- \* The applied exchange rates are the 2010 annual average exchange rates published by Oanda ([www.oanda.com](http://www.oanda.com)). Applying a single exchange rate to both 2009 and 2010 sales data eliminates possible fluctuations of market size and market growth due to exchange variations.
- \* The data regarding population and healthcare expenditure are from the annual OECD report.
- \* UK data does not reflect the market share of companies which do not participate in EDMS.
- \* Swiss data include Lichtenstein.

## About *In Vitro* Diagnostics:

*In Vitro* Diagnostics (IVDs) are non-invasive tests performed on biological samples to diagnose or exclude a disease. They are used for disease screening, therapy monitoring and to ensure the safety of the blood used in transfusions. IVDs have a broad scope ranging from sophisticated technologies performed in clinical laboratories to simple self-tests, such as for pregnancy.

## About EDMA:

EDMA, the European Diagnostic Manufacturers Association, represents national associations and major companies engaged in the research, development, manufacture or distribution of *In Vitro* Diagnostic (IVD) tests in Europe. Through its membership, EDMA represents in total more than 500 companies across Europe. The mission of EDMA is to raise awareness of the importance, usefulness and added value that diagnostic information can provide to healthcare. For this purpose, EDMA cooperates with European institutions, patients groups, trade associations, health professionals and academia to support an appropriate regulatory system, to work towards a realistic economic environment for healthcare in Europe and to be an effective voice in globalisation.

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